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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEBB, WALTER E	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,030	ABE ET AL.	
	Examiner	Art Unit	
	Walter E. Webb	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9 are pending and rejected.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For the purposes of examination, claims 7-9 will be treated as product claims.

Claim Rejections - 35 USC § 112

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating COPD, ARDS, or ALI does not reasonably provide enablement for prevention of COPD, ARDS, or ALI. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to

undue experimentation. The factors include:

1) the nature of the invention;

2) the breadth of the claims;

3) the predictability or unpredictability of the art;

4) the amount of direction or guidance presented;

5) the presence or absence of working examples;

6) the quantity of experimentation necessary;

7) the state of the prior art; and,

8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

Factors 1 and 2: The claimed invention is drawn to a therapeutic agent and method for preventing and/or treatment of pulmonary diseases that exhibits neutrophilic inflammation such as COPD, ARDS, or ALI.

Factors 3 and 7: In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the prevention of COPD, ARDS, or ALI, could be effectively achieved by the administration of the claimed active agent. Based on the state of the art, as discussed below, the artisan would have only accepted that the treatment of COPD, ARDS, or ALI could be achieved, rather than that such an agent could have been used to prevent COPD, ARDS, or ALI.

As set forth in *In re Marzocchi* et al., 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112 unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling."

Factor 4: Applicant disclosed guidance in the form of animal studies showing that the composition reduced neutrophils in the lung. Applicant also disclosed how a human or animal might be administered this composition. To enable the Artisan to reasonably predict that Applicant's composition can prevent COPD, ARDS, or ALI, Applicant should set forth stronger evidence. Applicant's disclosure is inadequate as to directing or guiding how the proposed agents can be employed to accomplish such objectives in a predictable manner.

Factor 5: The specification at pages 12-15 provides evidence demonstrating that the composition reduced the number of neutrophils in animals challenged with smoking induced pulmonary injury. While the present claims encompass prevention of COPD, ARDS, or ALI, Applicant's data merely establishes a reduction of neutrophils in the

lungs of injured animals. No data has been provided, or reasonable scientific basis exists, for treating such results as a prevention of COPD, ARDS, or ALI.

For example, treatment Chronic Obstructive Pulmonary Disease (COPD) is well developed (see Merck Manuel, Chronic Obstructive Pulmonary Disease (COPD): Merck Manual Professsional, http://www.merck.com/mmpe/sec05/ch049/ch049a.html.), but the state of the art with regard to preventing this disease, in general, is grossly underdeveloped.

In this regard, The Merck Manuel is cited. In particular, there is no known agent that is effective against preventing COPD. The Merck reference clearly shows that for the different symptoms associated with COPD and the severity of the disease, there is not one agent or combination thereof that is effective at preventing every symptom (see Symptoms and Signs pp. 3-4 and Treatment at pp. 9-12.).

Given that there was not known a specific agent or combination of agents effective to prevent COPD, one of ordinary skill in the art would not accept on its face Applicant's statement that such an objective could be achieved with COPD, ARDS, or ALI. The artisan would have required sufficient direction as to how to predict what particular types of pulmonary diseases would actually show sensitivity to the presently claimed composition such that the artisan would have been imbued with at least a reasonable expectation of success in preventing COPD, ARDS, or ALI. Such success would not have been reasonably expected for prevention of COPD, ARDS, or ALI given the variable nature of treating COPD known in the art. The prevention of COPD, ARDS, or ALI would have been an outcome not reasonably expected by one of ordinary skill in

the art. To the artisan, the concept of a single agent, or even a combination of agents, that is effective to prevent COPD, ARDS, or ALI would have been unique and, thus, met with a great deal of skepticism.

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in light of the state of the art, which recognizes the unpredictable nature of treating COPD, there is no apparent disclosure to support the contention that COPD, ARDS, or ALI can be prevented by simply administering, by any method, the claimed compound, since the present specification fails to enable one of ordinary skill in the art to practice the entirety of the presently claimed invention.

Factor 6: The burden of preventing COPD, ARDS, or ALI with the claimed compound is much greater than that of treating COPD, ARDS, or ALI, with the claimed compound. Since the present specification would not enable one of ordinary skill in the art to prevent COPD, ARDS, or ALI with the claimed compound, a clear burden of undue experimentation would be placed upon one of ordinary skill in the art in order to practice the full scope of the presently claimed invention.

Factor 8: In view of the discussion of each of the preceding seven factors, the level of skill in this art is high and is at least that of a medical doctor with several years of experience in the art.

Summary

As the discussion of the above 8 factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue one of ordinary skill in the art with

a reasonable expectation that prevention of COPD, ARDS, or ALI with the claimed compound could be achieved. In order to actually achieve such an objective, it is clear from the discussion above that one of ordinary skill in the art could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicant has failed to demonstrate, via direct evidence or sound reasoning, that COPD, ARDS, or ALI can be prevented with the claimed composition, one of ordinary skill in the art would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claims 1-9 are deemed properly rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 provide for the use of 7-[2- (3,5-dichloro-4-pyridyl)-l-oxoethyl]-4-methoxy-spiro[l,3- benzodioxol-2,1'-cyclopentane] but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

For the purposes of examination, claims 7-9 will be treated as product claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawakita et al., (EP 0771794).

Applicant's invention is drawn to a therapeutic or preventive agent or method for treating or preventing pulmonary diseases by administering a compound represented by formula I (claims 1, 4 and 7). Pulmonary diseases can be COPD, pulmonary emphysema, chronic bronchitis (claims 2, 5 and 8), ARDS or ALI (claims 3, 6, and 9).

Kawakita teach the compound represented by formula I. (See Table 7 at pg. 39 (compd. no. 140).) They teach that the compound exhibits phosphodiesterase IV inhibitory activity, which effect the infiltration of neutrophils, and have a therapeutic effect on respiratory obstructive diseases. (See page 3 lines 5-10 and 35-33) These diseases include COPD, emphysema, asthma, bronchitis, ARDS, and ALI. They also demonstrate how a compound may be prepared for administration in tablet form, powder, nasal inhalation, injection, suppository etc. (See preparation example 1-3 at page 140, preparation example 4-6 at page 141.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-28 and 33-35 of copending Application No. 10/567,127. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim the same compound to be used for treating the same pulmonary diseases.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 9:00am-5:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER